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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,168	03/12/2004	Michael Spiegel	LDP-8080 CIP	1047

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Michael Spiegel
199 Palm Avenue
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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT PAPER NUMBER

3735

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	10/801,168	SPIEGEL, MICHAEL	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) Christine D. Hopkins.

(3) Charles A. Marmor, II.

(2) Loren D. Pearson Reg. No. 42,987.

(4) Dr. Michael Spiegel.

Date of Interview: 23 October 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: _____.

Claim(s) discussed: 1-14.

Identification of prior art discussed: Canedo (U.S. Pub. No. 2003/0171640).

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

CDA

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Charles A Marmor, II
SPE, Art Unit 3735

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

The proposed amendment regarding the filing date of the Canedo (2003/0171640) reference applied in a 102(e) rejection appears to obviate the rejection. The discussion of the 102 rejection focused on the alleged differences between the prior art and proposed claim language. The position taken by the applicant addressed the alleged differences between the instant application and the prior art stating the strength of electric field applied to a patient in the prior art failed to produce the magnitude of that disclosed by applicant. Further, applicant addressed the 103 rejections while taking the position that simply scaling a coil to necessary dimensions that would be applicable to applicant's invention would render the invention inoperable. The Examiner noted that the search would be updated upon submission of a formal amendment.

PROPOSED DRAFT RESPONSE-NOT FOR FORMAL ENTRY

Certificate of Transmission

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office (Fax No. (571)273-8300).

By: _____ Date: October 17, 2006
Loren Donald Pearson

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Confirm. No. : 1047
Appl. No. : 10/801,168
Applicant : Spiegel, Michael
Filed : 03/12/2004
Art Unit : 3735
Examiner : Hopkins, Christine D.
Title : Apparatus for Creating Therapeutic Charge
Transfer in Tissue
Docket No. : LDP-8080CIP
Customer No. : 54962

PROPOSED DRAFT AMENDMENT

Mail Stop No-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner Hopkins:

This "Proposed Draft Amendment" is not to be a formal response. Rather it is offered to prepare the Examiner for a telephonic interview with the Applicant and the undersigned attorney.

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PROPOSED DRAFT AMENDMENT--NOT FOR OFFICIAL FILING

Responsive to the supplemental Office action dated September 15, 2006, kindly amend the above-identified application as follows:

Amendments to the Specification begin on page 3 of this paper.

Amendments to the Claims are reflected in the listing of claims that begins on page 7 of this paper.

Amendments to the Drawings begin on page 15 of this paper and include thirteen (13) attached replacement sheets and one (1) annotated sheet showing changes.

Remarks/Arguments begin on page 16 of this paper.

An Appendix including thirteen replacement sheet of drawing figures and one annotated sheet of drawings is attached following page 45 of this paper.

Appendix II is an article: Reich and Tarjan, "Electrical Stimulation of Skin," 29 Intl J. of Derm., No. 6 395 (July-August, 1990).

Apendix I, Declaration under Rule 1.132.

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In the Specification:

Replace the paragraph beginning at page 36, line 2, with the following:

--Fig. 1 is a perspective view of a rotating disk like member;

Fig. 2 is a perspective view of the individual magnets of the disk like member shown in Fig. 1;

Fig. 3 is a plan view of a motor driven treatment system using the rotating disk like member;

Fig. 4 is a perspective view of an alternate embodiment of the rotating disk like member utilizing a plurality of permanent magnets forming a portion of the outer peripheral surface;

Fig. 5 is a cross-sectional view of the disk like member of Fig. 4 taken along line I-I;

Fig. 6 is a perspective view of an alternate embodiment with an electromagnet generates a stepwise changing magnetic field;

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Fig. 7 is a graph plotting the magnetic and resultant electric fields generated by all the embodiments of this invention versus time;

~~Fig. 8 is a plan view of an embodiment of a treatment system using the stepwise changing electromagnet wherein full articulation of system is provided~~ was duplicative of Fig. 6 and has been canceled;

Fig. 9 is a perspective view of a transdermal medicant delivery device using a stepwise changing magnetic field to induce the transport of the medicant;

Fig. 10 is a cross-sectional view of Fig. 9 taken along line J-J;

Fig. 11 is a diagrammatic front view of an electromagnetic coil embodiment of the apparatus according to the invention;

Fig. 12 is a block diagram of the electromagnetic coil embodiment of the apparatus;

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Fig. 13A is a block diagram showing a circuit of the electromagnetic coil embodiment connected to ground during the charging part of the cycle;

Fig. 13B is a block diagram showing the circuit disconnected to the ground and connected through a ballast resistance during the discharge part of the cycle;

Fig. 14A is a perspective exploded view of the coil;

Fig. 14B is a perspective view of the coil;

Fig. 14C is a section view of the coil taken along line A-A in Fig. 14B;

Fig. 15A is a graph plotting relative voltage per centimeter of the coil versus time;

Fig. 15B is a graph plotting magnetic field strength of the coil on the same time axis as Fig. 15A; and

Fig. 16 is a graph plotting typical magnetic and electric field strengths of a coil versus time.--

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Replace the paragraph beginning at page 46, line 3, with the following:

--Fig. & 6 shows a typical embodiment for the therapeutic application. Power supply 21 energizes coils 17 on core 16 5 through controller 20. The angle of the outer magnetic face of the core 16 is controlled by a dual axis assembly 10. The outer magnetic face core 16 is separated from the treated biological material by a protective guard 11. The protective guard is made of non-conducting material such as glass-10 reinforced plastic or some other non-magnetic and nonconducting plastic. The height of the outer magnetic face of core 16 is controlled with gear track 9 mounted on stand 8.--

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In the Claims:

Claim 1 (Currently Amended). An apparatus for creating therapeutic charge transfer in tissue, comprising a coil generating a changing magnetic field to induct an electric field in the tissue exceeding ~~10~~ 1 mV/cm when said coil is 5 cm from the tissue.

Claim 2 (Original). The apparatus according to claim 1, wherein said magnetic field is saw-tooth shaped.

Claim 3 (Original). The apparatus according to claim 2, wherein said magnetic field has a growth phase and a decay phase, a duration of said growth phase being at least ten times a duration of said decay phase.

Claim 4 (Original). The apparatus according to claim 3, further comprising a control circuit controlling a current fed to said coil, said control circuit including two subcircuits and a switch for switching between a first of said subcircuits and a second of said subcircuits, said first of said subcircuits causing said growth phase, said second of said subcircuits causing said decay phase.

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Claim 5 (Original). The apparatus according to claim 4, wherein:

each one of said subcircuits has a respective λ equaling an inductance (L) divided by a resistance (R) of said respective one of said subcircuits; and

said λ of said second subcircuit is at least ten times said λ of said first subcircuit.

Claim 6 (Original). The apparatus according to claim 4, wherein said first subcircuits has a λ no greater than 1, λ being calculated by dividing a resistance (R) of said first subcircuit by an inductance (L) of said first subcircuit.

Claim 7 (Original). The apparatus according to claim 4, wherein said second subcircuit has a λ no less than 10, λ being calculated by dividing a resistance (R) of said second subcircuit by an inductance (L) of said second subcircuit.

Claim 8 (Original). The apparatus according to claim 4, wherein said second subcircuit includes an IGBT for increasing a resistance of said second subcircuit.

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Claim 9 (Original). The apparatus according to claim 1, wherein said coil is configured to receive a current exceeding 2000 V.

Claim 10 (Original). The apparatus according to claim 1, wherein said coil has a duty cycle of at least ten percent.

Claim 11 (Original). The apparatus according to claim 10, wherein said coil has a duty cycle of at least eighty percent.

Claim 12 (Original). The apparatus according to claim 1, wherein said coil is liquid cooled.

Claim 13 (Original). The apparatus according to claim 12, wherein said coil is cylindrical and has an inner channel and an outer channel through which coolant can be passed to cool said coil.

Claim 14 (Original). The apparatus according to claim 1, wherein said magnetic field has an asymmetric waveform.

Claim 15 (New). The apparatus according to claim 1, wherein said coil generates a changing magnetic field to induct an

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electric field in the tissue exceeding 10 mV/cm when said coil is 5 cm from the tissue.

Claim 16 (New). A method for magnetically inducing an electrical field in tissue to create therapeutic charge transfer in the tissue, which comprises:

providing an apparatus according to claim 1;

increasing the magnetic field in said coil to induct an electrical field having a first direction in the tissue for a first period of time; and

decreasing the magnetic field to induct an electrical field having a second direction opposite said first direction in the tissue for a second period time, the second period of time being different than said first period of time..

Claim 17 (New). The method according to claim 16, wherein the first period of time is longer time than the second period of time.

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Claim 18 (New). The method according to claim 16, which further comprises repeating the increasing step and the decreasing step.

Claim 19 (New). The method according to claim 16, wherein:

the increasing of said magnetic field occurs nearly linearly over time; and

the decreasing of said magnetic field occurs nearly linearly over time.

Claim 20 (New). The method according to claim 16, wherein the increasing and the decreasing of said magnetic field has a saw-tooth shaped intensity over time, wherein said saw-tooth shaped intensity increases nearly linearly and decreases nearly linearly.

Claim 21 (New). The method according to claim 16, wherein said first period of time is at least five times as long as said second period of time.

Claim 22 (New). The method according to claim 16, wherein the increasing of said magnetic field includes increasing said

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magnetic field at a sufficient rate so that said electric field in the tissue is at least 1 mV/cm.

Claim 23 (New). The method according to claim 16, wherein the increasing of said magnetic field includes increasing said magnetic field steadily so that said electric field varies less than 10% in intensity for at least 90% of said first period of time.

Claim 24 (New). The method according to claim 17, which further comprises minimizing said second period of time.

Claim 25 (New). The method according to claim 16, which further comprises:

repeating the increasing and the decreasing steps in alternating order;

defining a duty cycle as said first time period divided by a sum of said first and second time period; and

maintaining said duty cycle to at least sixty-three percent.

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Claim 26 (New). The method according to claim 16, which further comprises:

creating an ionic charge transfer in the tissue in a first direction during the increasing step; and

creating an ionic charge transfer in the tissue in a second direction opposite said first direction during the decreasing step; and

controlling a rate of change of said magnetic field and duration of the increasing step and the decreasing step so that said charge transfer in said second direction is no more than half said charge transfer in said first direction.

Claim 27 (New). The method according to claim 16, which further comprises:

creating said magnetic field in a coil;

connecting said coil to an increase subcircuit that feeds current to said coil during the increasing step; and

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connecting said coil to a decrease subcircuit that robs current from said coil during the decreasing step.

Claim 28 (New). The method according to claim 27, which further comprises:

interconnecting said coil and said increase subcircuit with an IGBT; and

interconnecting said coil and said decrease subcircuit with said IGBT.

Claim 29 (New). The method according to claim 28, wherein said IGBT has a stand-off voltage of at least two thousand volts.

Claim 30 (New). The method according to claim 27, which further comprises:

passing an electrical current through said coil to create said magnetic field; and

during the increasing step, raising said electrical current to at least one thousand watts.

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Amendments to the Drawings:

The attached 13 sheets of drawings includes replacement line drawings for all of the originally-submitted figures. No new matter has been added.

Fig. 8 has been canceled because it is identical to Fig. 6 and is reflected in the annotated sheet. The brief description has been amended to reflect the cancellation.

Attachment: 13 Replacement Sheets

1 Annotated Sheet Showing Canceled Fig. 8

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Remarks:

Reconsideration of the application is requested. Claims 1-30 are now in the application. Claim 1 has been amended. Claims 15-30 have been added.

Claim 1 was amended to broaden the scope of the claimed invention. Support for the change to claim 1 can be found in the originally filed specification at page 50, line 16. The amendment to claim 1 was not made for reasons relating to the prior art or the statutory requirements for obtaining a patent. Claim 15 was added and is identical to the originally-filed claim 1 in scope.

Claims 16-30 relate to a method of using the apparatus according to claim 1. Such method claims should be rejoined and allowed when the underlying base claims (i.e. claim 1-15) are allowed. See MPEP § 821.04(b).

With regard to claims 19-20, the term "nearly" is used. Applicant uses the word "nearly" in recognition that empirically the growth and decay occur asymptotically in a manner that approaches but never truly reaches linearity. Read in this light, claim 20 should be definite. If the Examiner is not

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satisfied, the Examiner is asked to call the undersigned attorney so that replacement language can be entered by telephone amendment.

Before addressing the rejections made by the Examiner, Applicant offers some the following insight to the invention.

The prior art has demonstrated that (direct current) electrical stimulation of tissue can be therapeutic. The key underlying science was not at all understood until the breakthrough analysis of Reich and Tarjan using direct (as opposed to inducted) fields; a copy of this paper is included as Appendix II. After a detailed study of a number of diverse and independent applications of electrical therapies, a clear and unequivocal conclusion emerged. Only in those applications where a sufficient quantity of electrical charge was caused to be transported across the wound site would a beneficial outcome be observed. The authors further conclude that two parameters are paramount in judging between various electrical modalities: "These two parameters are the average spatial current density and the effective duty cycle. These parameters can be combined with the treatment time to provide the absolute charge density transferred."

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As discussed in the prior-art section of the instant application, the treatment of tissue by direct application of current to treat tissue, especially nervous tissue, is limited in practice due to the associated risk of infection.

The primary objective of the instant application is effective charge transport in tissue created by specific electric fields that are induced by related magnetic fields. It follows, that the claims are directed to an apparatus that has the mechanical features to achieve this objective. Applicants review of the prior art leads them to concluded that none of the cited references teach or suggest an apparatus capable of achieving the object; the reasons are detailed below.

The instant application teaching provides an apparatus and a method to achieve the objective: high electric field strengths, long effective duty cycles, and the ability to repeat the process (cycle) continuously for an uninterrupted extended duration achieve absolute charge transport.

While the Applicant acknowledges that the various separate components of the current teaching are known: in themselves, they are not novel. However, the apparatus and method that

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combine and utilize the various elements is novel and not obvious. No other cited or known method of therapeutic electrical induction is able to produce the combined requisite electrical outputs taught herein.

Now referring to the specific rejections in the Office action, in item 3 of the Office action, the Examiner rejected claims 2 and 14 as being directed to non-statutory subject matter. More specifically, the Examiner stated that, "The positive recitation of the shape of the magnetic field wave is not statutory subject matter." MPEP § 2106 sets the examination guidelines for interpreting 35 U.S.C. § 101. "USPTO personnel must first identify whether the claim falls within at least one of the four enumerated categories of patentable subject matter recited in section 101 (i.e., process, machine, manufacture, or composition of matter);" MPEP §2106.IV.B. The Examiner must then determine if the claims are directed to nothing more than abstract ideas, natural phenomena, and laws of nature; MPEP § 2106.IV.C. To be patentable the claimed invention must be a practical application of an abstract idea, law of nature, or natural phenomenon; MPEP §2106.IV.C.2. The practical test is whether the invention as claimed "(A) 'transforms' an article or physical object to a

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different state or thing; or (B) otherwise, produces a useful concrete, and tangible result..."

Claims 2 and 14 and their intervening base claims are repeated *inter alia* below.

Claim 1 (Currently Amended). An apparatus for creating therapeutic charge transfer in tissue, comprising a coil generating a changing magnetic field to induct an electric field in the tissue exceeding 1 mV/cm when said coil is 5 cm from the tissue.

Claim 2 (Original). The apparatus according to claim 1, wherein said magnetic field is saw-tooth shaped.

Claim 14 (Original). The apparatus according to claim 1, wherein said magnetic field has an asymmetric waveform.

To begin the Section 101 analysis, claims 1, 2, and 14 are all directed to an "apparatus". An apparatus is a machine, which is one of the enumerated exceptions in the statute.

Next, the invention as described in claims 2 and 14 is patentable subject matter because it involves an apparatus that applies a specific waveform, which is a phenomena of nature, to produce a useful concrete, and tangible result. The apparatus has been studied at the University of Miami Medical School, The Miami Project to Cure Paralysis, Advanced Wound Recover of

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Boston, and Johns Hopkins Medical School to obtain therapeutic results. For example, *in vivo* tests have been conducted in which burns on pigs were treated using the apparatus. The wounds that were treated healed faster than untreated wounds in the control wounds. Appendix I provides a report of the experiment and results.

Claims 2 and 14 are directed to apparatuses that create therapeutic charge transfer in tissue by generating a saw-tooth or asymmetric shaped magnetic field to induct an electric field in the tissue exceeding 10 mV/cm when said coil is 5 cm from the tissue. The invention is useful because treating tissue by placing it near the magnetic field creates a charge tissue within the tissue, which in turn promotes healing. The invention described is tangible because the apparatus is more than merely recited; structures such as the coil are specified in the base claim, claim 1. The invention creates a concrete result; the device has been used repeatedly to produce results; *see for example* Appendix I.

Applicants are not intending to claim a waveform. Rather, Applicants intent is to claim an apparatus that uses a coil to generate a magnetic field to treat tissue. Creating and

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utilizing magnetic fields with specific qualities (i.e. claims 2 and 14) with the device have been discovered to have therapeutic utility. Inventors do not intend to claim the waveform and prevent others from using it with different devices in different applications.

For these reasons, claims 2 and 14 when read with the limitations of their underlying base claim, claim 1, are the type of statutory subject matter that is to be patentable under 35 USC § 101.

In item 5 of the Office action, the Examiner rejected claims 1-3 and 14 as being fully anticipated by Canedo (US 2003/0171640) under 35 U.S.C. § 102(e).

Applicant respectfully notes that Canedo has a filing date of March 8, 2002. See 35 U.S.C. § 102(e). As set forth in the Declaration of record, the instant application is a continuation-in-part application of copending U.S. Application 10/035,854, filed November 9, 2001, now abandoned. Pursuant to 35 U.S.C. § 120, applicant is entitled to the priority date of the parent application. See MPEP § 201.11. Section 201.11 further explains, "Any claim in a continuation-in-part

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application which is directed solely to subject matter adequately disclosed under 35 U.S.C. 112 in the parent nonprovisional application is entitled to the benefit of the filing date of the parent nonprovisional application."

To support the domestic priority claim, the rejected claims are mapped in the following to the specification of the parent application.

Claim 1 (Currently Amended). An apparatus for creating therapeutic charge transfer in tissue (p.7, ll 9-19), comprising a coil generating a changing magnetic field (p.10, l. 19 - p.11, l. 18) to induct an electric field in the tissue (p.7, l.11) exceeding 1 mV/cm when said coil is 5 cm from the tissue (p.25, l.13).

Claim 2 (Original). The apparatus according to claim 1, wherein said magnetic field is saw-tooth shaped (Fig. 7).

Claim 3 (Original). The apparatus according to claim 2, wherein said magnetic field has a growth phase and a decay phase, a duration of said growth phase being at least ten times a duration of said decay phase (Fig. 7).

Claim 14 (Original). The apparatus according to claim 1, wherein said magnetic field has an asymmetric waveform (Fig. 7).

Thus, the claims 1-3 and 14 adequately disclosed under 35 USC § 112 in the parent application. Because the instant application

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can claim the parent application's filing date, the instant application effectively predates Canedo. Because Canedo was filed after the priority date of the instant application, applicant respectfully believes that Canedo is unavailable as prior art.

Therefore, applicant respectfully submits that the Section 102 rejection in item 5 is now moot.

If the Examiner were not to grant the priority and remove Canedo, Canedo still does not anticipate claims 1-3 and 14. As will be explained below, the claims were patentable over the cited art in their original form and the claims have, therefore, not been amended to overcome the references.

Before discussing the prior art in detail, a brief review of the invention as claimed is provided. Amended claim 1 calls for an apparatus for creating therapeutic charge transfer in tissue that includes the following:

a coil generating a changing magnetic field to induct an electric field in the tissue exceeding 1 mV/cm when said coil is 5 cm from the tissue.

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Although Canedo '640 teaches a coil for magnetically inducing therapeutic electric fields, Canedo does not teach "to induct an electric field ... exceeding 10 mV/cm" as provided in Claim 1 of the instant application.

The Examiner's analysis of the prior art includes a mischaracterization of Canedo '640. In item 5 of the Office action, the Examiner stated, "With reference to claims 1-3 and 14, Canedo '640 teaches a coil for inducing an electric field exceeding 10 mV/cm when the coil 119 is distanced around 5 cm from the tissue as evident in Fig. 6." (Emphasis added by Applicant.)

Canedo '640 does not teach to induce an electric field exceeding 10 mV/cm. Although the Examiner contends that Fig. 4 indicates an output voltage to the coil, this is actually incorrect. In fact, the brief description reads as follows: "Fig. 4 shows a graphic representation of the waveform generated by the electric current supplied to the coils by the electrical circuit in all embodiments of the apparatus of this invention." (Emphasis added by Applicant.) In addition in paragraph 0104 of Canedo '640, the publications states the following: "The relationship between the instantaneous current supplied by the electric circuit to

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the magnetic coils as a function of time are shown as a series of waves in the forms shown in Fig. 4." (Emphasis added by Applicant.)

Fig. 4 of Canedo '640 shows a graphic indication of an average line voltage of 10 mV. It is very important to delineate between a simple voltage, which describes only the scalar value of one of a circuit's power components (voltage and current), and the description of vector component of an electric field, which is always given as electromotive force/unit of distance, such as volts/meter or mV/cm. The term "1 mV/cm" used in Claim 1 of the instant application specifies an electric field generated in space above the surface of the coil and is the output of the claimed apparatus.

Clearly, Canedo '640 does not teach a 10 mV/cm output electric field as recited in Claim 1 of the instant application.

Claims 2-3 are patentable over Canedo '640 for the additional reason that Canedo '640 does not teach a magnetic field that is saw-tooth shaped. Claim 2 (and, therefore, claim 3, which depends on claim 2) states that the magnetic field created in the coil "is saw-tooth shaped." While, for the reasons

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discussed below, Applicant does not concede that the input line voltage shown in Fig. 4 is "saw toothed", even if the voltage shown in Fig. 4 were in *arguendo* considered saw-tooth shaped, the electric field shown is the input electric field and not the resulting output magnetic field. To repeat, the instant application claims a "saw-tooth shaped" magnetic field. The resulting (i.e. output) magnetic field is used to induce the output electric field in the tissue.

Although Fig.4 of Canedo '640 specifically describes only the input voltage to the coil, it might be argued that a similar shaped magnetic field would be produced by the coil. While such a result may be possible, Applicant's research and development have shown that generating such a result requires the manipulation of many variables associated with both the circuit and geometry of the coil. It is well established physics that coil design is not a linear progression and, therefore, variation of any parameter can and does cause large, nonlinear changes in many other parameters. Applicant asserts that it is not the classical and well-defined shape used by those with ordinary skill in the art. Applicant is a Ph.D. in physics and has spent several years developing the equipment to generate the desired magnetic saw-tooth waveform.

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Even if such a similarly shaped magnetic field were produced by the coil in Canedo '640, it would not, by any possible calculation, produce an OUTPUT induced electric field greater than 10 μ v/cm (that is 1,000 times smaller than 10mv/cm described in claim 1 of the instant application). As an example, the DC portion of induced electric field according to the invention requires an INPUT voltage to the coil of 80 volts. That is 8,000 times greater than the average input voltage taught by Canedo '640 and 4,000 times greater than the peak input voltage taught by Canedo '640.

The invention as claimed is distinguished from Canedo '640 the resulting induced electric field is multiples of ten smaller than the electric field strength (i.e. 10 mV/cm) claimed in the current invention. To generate an electrical field having the claimed strength and magnetic waveform, the Applicant needed to conduct significant research and combine switches (large IGBTs) and coils in never-before known combinations. In light of this required research, the Examiner should not overextend the teachings of Canedo '640 (and likewise Ryaby and Abbott) to simply suggest a scaling up of inventions to yield a circuit that induces an electric field with the claimed strength. Although the time varying magnetic field that Canedo '640

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generates will produce an induced electric output that, like those of Ryaby and Abbott, may appear similar to the electric output according to the invention of the instant application, the prior-art electric field strengths are orders of magnitude smaller. Furthermore, none of the prior-art systems can be scaled to the level that the instant application teaches using the systems and circuits disclosed in the application.

For the previously-discussed additional reasons, Canedo '640 neither teaches nor suggests generating a saw-tooth shaped magnetic field to induct an electric field having a strength of 10 mV/cm.

In item 7 of the Office action, the Examiner rejected claims 4-7 as being unpatentable over Canedo '640 in view of Tysb '400 and Kurtz '922 under 35 USC § 103(a).

Claim 4 describes, in an apparatus for creating therapeutic charge transfer in tissue utilizing a coil to generate a changing saw-toothed magnetic field to induct an electric field in the tissue exceeding 10 mV/cm when the coil is 5 cm from the tissue, wherein the magnetic field has a growth phase lasting at least ten times a duration of a decay phase:

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a control circuit controlling a current fed to said coil,

said control circuit including two subcircuits and a switch for switching between a first of said subcircuits and a second of said subcircuits,

said first of said subcircuits causing said growth phase,

said second of said subcircuits causing said decay phase.

Canedo '640 has been distinguished previously in this response.

With regard to Tsyb et al. '400, Applicants disagree with the Examiner's conclusion that Tsyb et al. '400 teaches, "A controlled switching element 5 (refer to Fig. 2) located between 'subcircuits' and connected to a unit 6 for controlling the slope of the leading edge, or growth phase of the magnetic pulses." Claims 4-7 depend on claims 2 and 3, which claim the saw-toothed magnetic field wherein the growth phase is at least ten times as long as the decay phase. The process of Tsyb et al. '400 will generate a single combined magnetic pulse that will produce a short DC like segment of electric field followed by a totally symmetric reversal of that electric field. Applicant's studies have shown that such symmetric waveforms do not produce the desired charge transport. A symmetric waveform merely produces a net charge transport of zero; it moves charge

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in one direction and then an equal amount in the opposite direction. This symmetric wave form violates the features of claims 2-3.

Applicant notes that the actual electrical field output of Tsyb et al. '400 is limited by the circuit to the same low duty cycle as those of Canedo '640, Ryaby, and Abbott; compare claims 10-11 of instant application. In column 9, lines 19-22, Tsyb et al. '400 teaches the pulse duration and number during a 2.5 minute treatment period. This allows calculation of the Duty Cycle - $50 \text{ cycles} \times 0.0003 \text{ seconds} / (2.5 \text{ minutes} \times 60 \text{ seconds/minute}) = 0.01\% (0.0001)$. At no point in the patent does Tsyb et al '400 specify an input or output current or voltage value.

Tsyb et al. '400 teaches multiple identical capacitive charging circuits that are sequentially "turned on" by a mechanical switch and then allowed to decay in the same circuit. The duty cycle demonstrated shows that there is no second decay circuit and thus no differential lambda that is required according to the Applicant's research. The "specify[ing of] an input or output current or voltage value" is just a further indication of Tsyb et al. failing to realize the mechanism of charge transport.

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The Examiner should note that this type of work cycle is the norm for all known prior-art systems. Tsyb et al. '400 achieves a strong output voltage (which reverses) by discharging (or actually allowing to decay) a capacitor that then requires a long period to recharge. By having to wait for the decay of the capacitor, the duty cycle is significantly decreased to what Applicants generally believe is an insignificant level, especially for the healing mechanism being harnessed by the invention of the instant application.

To begin, Applicant agrees with the Examiner that the creation of the claimed magnetic field was reduced to practice by applying basic rules of physics. The Examiner stated, "Kurtz teaches that the rise and fall times, or growth and decay times ... may be controlled by the inductance of the coil." The Examiner also noted, "In view of the teachings that the resistance and inductance of each subcircuit can be varied in such a manner as to provide a time constant that may be ten times greater in one circuit than the other." Applicant admits that it is well known that growth and decay of magnetic fields generated by electric coils being charged or discharged obey physical laws that are dependent on the resistance, inductance, and capacitance of the circuit. Furthermore, Applicant

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acknowledges that it would be obvious to vary the ratios of resistance and inductance to achieve decay or growth times that can exceed ratios of 10.

With reference to Kurtz '922, Applicant believes that the prior art's misteachings of impossible to create phenomena as well as the Examiner's acceptance of them, prove that the switching according to the invention as claimed is not obvious. Applicant also notes that Fig. 11 of Kurtz '922 shows stepped increases (i.e. vertical increases) of the magnetic field of a coil generated by current pulses. However, the Examiner should recognize that empirically speaking, because of the previously-discussed physics and coil theory, such "square edged" steps would be empirically impossible because they show no growth phase. Applicant points this out to illustrate the apparent lack of obviousness to both Kurtz and the Examiner of his patent.

Comparing Kurtz '922 to the invention of the instant application, Kurtz '922 shows no system that would produce an electric field that would produce charge transport. (Net) charge transfer is the object of the invention of the instant application.

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Kurtz may have almost understood the principal (i.e. charge transport) of the invention of the instant application but ultimately failed to provide a device that would be efficient enough to apply the theory. Kurtz '922 separates the growth and decay phases of the magnetic field in order to allow the effect of the initially induced electric field not to be negated by the opposite polarity of the decay phase. Here Kurtz shows that he may have understood that the symmetrical decay of the magnetic field would not produce a therapeutic effect. Still, despite the possible realization, Kurtz was unable to devise a second circuit with a much more rapid decay time. Kurtz's teaching (i.e. waiting for a long delay between the growth and decay phase) produces a very low duty cycle as the delay time between phases reduces the time of the active initial field.

Applicants believe that the rejection in item 7 was an improper use of hindsight. The mere piecing together of elements from the prior art is not enough to form a *prima facie* case of obviousness. In making this rejection, the Examiner argued that because Canedo '640 (shown to be vitiated) in view of Tsyb et al. '400 (mentions a switch for a system with a duty cycle of 0.01%) and Kurtz '922 (not intended for charge transport, having errors of fact, and low duty cycle) each mentioned a feature of

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the claimed invention, therefore one with ordinary skill in the art would believe that the invention as claimed is obvious.

A critical step in analyzing the patentability of claims pursuant to 35 U.S.C. § 103 is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614,1617 (Fed. Cir. 1999). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *Id.* (quoting *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Most if not all inventions arise from a combination of old elements. See *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453,1457 (Fed. Cir. 1998). Thus, every element of a claimed invention may often be found in the prior art. See *id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole

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claimed invention. See *id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the appellant. See *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 163.5, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. See *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. See *WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981) (and cases cited therein). Whether the examiner relies on an express or an implicit showing, the examiner must provide particular

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findings related thereto. See *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. Broad conclusory statements standing alone are not "evidence." *Id.* When an examiner relies on general knowledge to negate patentability, that knowledge must be articulated and placed on the record. See *In re Lee*, 277 F-3d 1338, 1342-45, 61 USPQ2d 1430, 1433-35 (Fed. Cir. 2002).

Upon evaluation of the examiner's comments, it is respectfully believed that the evidence adduced by the examiner is insufficient to establish a *prima facie* case of obviousness with respect to the claims. Accordingly, the examiner is requested to withdraw the rejection.

Accordingly, none of the references, whether taken alone or in any combination, either show or suggest the features of claim 4. Therefore, claim 4 is patentable over the art. Moreover, because claims 5-7 are ultimately dependent on claim 4, they are believed to be patentable as well.

In item 8 of the Office action, the Examiner rejected claim 8 as being unpatentable over Canedo '640 in view of Tsyb et al. '400, Kurtz '922 and Mangano '768 under 35 USC § 103.

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Claim 8 calls for an apparatus having the following features:

a second subcircuit including an IGBT for increasing a resistance of said second subcircuit.

In item 8 of the Office action, the Examiner recapitulated that, "The combination of Canedo, Tsyb, and Kurtz disclose the invention as claimed". The examiner also states, "Mangano teaches the induction of a magnetic field within a cellular suspension. With respect to claim 8, Mangano '786 discloses and IGBT for providing enhanced current and voltage capabilities."

Unlike the invention, the magnetic field referred to by Mangano '786 is not considered as part of his disclosed application: "The electric field applied to the cell suspension is created by an electric signal applied to the electrodes; however, it is also contemplated that the electric field can be induced in the sample cell via induction by a magnetic field." This quote demonstrates that the IGBT named was not used as an inductive switch. Rather, the IGBT named is used as a switch for a capacitor. Mangano '786 says (col. 47, lines 57-65), "A stack of integrated bipolar transistors (IGBTs) 185 and 187, which are solid state switches that apply the electrical energy stored in the storage capacitors 184 to the PEF treatment cell."

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It is again not an issue that IGBTs are used as switches for high voltage and high current applications. That is why they are made and there are well known and numerous examples of this use. The issue again is the object of the invention: inductive charge transport. The invention of the instant application teaches a novel method that combines known materials and science in a novel and non-obvious way. The IGBT component is claimed to delineate this apparatus from all others previously referenced or cited to produce induced therapeutic electrical medical treatment.

Because none of the prior art teach using this combination in the field of induced therapeutic electrical medical treatment, the claim 8 is not obvious and patentable.

In item 9 of the Office action, the Examiner rejected claim 9 as being unpatentable over Canedo '240 in view of Manni '976 under 35 USC § 103(a). The rejection builds on the previous rejections based on Canedo '240 and adds Manni '976 to teach a high-energy coil.

Applicant responds by reemphasizing the previously detailed distinctions between the invention and Canedo '640.

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Furthermore, the invention requires more than just an upscaling of the voltage. A system like in Canedo '640 is not possible to operate at significantly higher voltage due to limits imposed by basic physics. If a system like in Canedo '640 could be taken to a high voltage and then allowed to decay naturally, the decay period would be symmetrical (i.e. no charge transport) and would take a long time (i.e. low duty cycle). To overcome these problems, the Applicant has learned to switch to a second subcircuit with a high resistance created by an IGBT.

Because a mere combination of Canedo '640 with Manni '976 would not lead one with ordinary skill in the art to a device that produces effective charge transfer, the invention according to claim 9 would not be obvious.

In item 10 of the Office action, the Examiner rejected claims 8 and 10 as being unpatentable over Canedo '640 in view of Litovitz et al. '665 under 35 USC § 103(a). The Examiner's rejection was based on the following statements. "With respect to claims 10 and 11, Litovitz teaches a coil generating a duty cycle between 10 percent and 90 percent of a field imposed on a living system (col. 12, lines 29-36)." The Examiner further stated that, "Therefore at the time of the invention it would

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have been obvious for one of ordinary skill in the art to have incorporated the duty cycle as taught by Litovitz to the invention of Canedo in order to retain an effective therapeutic field."

Litovitz '665 shows very clearly that the duty cycle to which he refers is for the purpose of interrupting exposure to electromagnetic radiation in the near 60 Hertz range, which he deems to be detrimental. He has examples of this in his Figs. 3, 4, 5, 6, and 7. His preferred method is to actually superimpose a modulating field on the incoming line signals that are a direct electrical connection to the circuit. He does mention that a similar effect may be obtained by alternately powering a coil on and off to produce an interfering electromagnetic field near the environment to be protected: that is, turn on and off the power to an electric coil to modulate the source of an external electromagnetic signal. In the citation given, he says, "Another method of modulating the detrimental field is by using square wave modulation. That is, interrupt the power delivered at a regular interval. The modulation frequency should be preferably of the order of one second, as guided by the Litovitz invention. The interruption

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time should be preferably between 0.1 and 0.9 seconds, corresponding to a duty cycle between 10% and 90%."

The term duty cycle can have more than one interpretation. It is usually defined as the percentage of time during the operation of a system in which it is doing work. It can also refer to that portion of a single cycle that is doing work. In claims 10 and 11 of the instant application, the duty cycle is referencing the on and off periods within each cycle of electric field generated by the machine. Because the same waveform inducing the electric field is repeated continuously without any intervening time for the entirety of the treatment period, the duty cycle of one wave period would be the same as the duty cycle for the entire exposure time of the treatment.

Beyond the admittedly obvious significance of increased efficiency, Applicants have found that duty cycle is critical to achieve charge transport. For a high energy electric coil to charge and discharge in the manner needed to achieve a duty cycle of 80%, the coil must have the very specific circuits taught in the instant application. To make it very plain, no system mentioned in the Detailed Action has the ability to produce continuously repetitive induced electric fields of

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output electric field strengths where the active DC like component of the cycle is both 80% of the cycle and greater than or equal to 1 mv/cm.

The specific duty cycle claimed is necessary to produce charge transport. Litovitz produces only a weak signal at approximately 60 Hertz, which according to Litovitz, is intended to "confuse the biologic cell so that it can no longer respond to the usual fields found in the home and work place." One with ordinary skill in the art reading Litovitz would require a great leap of insight to move from the teaching of Litovitz to reach the combination of claims 10-11. Litovitz teaches that a signal turned on and off at any duty cycle and can be used to "confuse" other low-energy, low-frequency signals. This does not suggest that modifying the duty cycle of Canedo '640 according to Litovitz would result in therapeutic charge transfer in tissue. Therefore, one reading Canedo '640 in light of Litovitz would not think that claims 10-11 are obvious.

In item 11 of the Office action the Examiner rejected claims 12 and 13 as being unpatentable over Canedo '640 in view of Day et al. '210 under 35 U.S.C. § 103(a).

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Applicants acknowledge that liquid coolant systems are not novel in and of themselves. However, when combined with the system as taught by Applicant (for the reasons discussed previously), the combination is patentable. Still, the invention of the instant application is running at such higher powers than those taught by the prior art in the therapeutic field that none have need liquid coolant systems. It is well known that the amount of heat produced by current passing through a wire is proportional to the electrical current squared, multiplied by the total resistance of the wire, $H = i^2 \times R$. The purpose of claims 12-13 was to delineate the coil required by the invention of the instant application, which requires a special cooling apparatus because of the amount of electrical power it uses. All cited prior-art inductive therapeutic systems do not require liquid cooling. This is because they are all incapable, by reason of the circuit design, of carrying high levels of continuous input current and thus incapable of providing the requisite output electric field required to produce charge transport of sufficient quantity to effect the desired therapeutic result. This suggests that the invention as claimed is more than a mere scaling up of devices like Canedo '640. Scaling up of the prior art, if possible, would lead to unforeseen challenges like a cooling system. For these reasons, the invention as described

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in claims 12-13 would not be obvious to one with ordinary skill in the art when reading Canedo '640 in view of Day et al. '210.

In view of the foregoing, reconsideration and allowance of claims 1-30 are solicited. In the event the Examiner should still find any of the claims to be unpatentable, please telephone counsel so that patentable language can be substituted.

A payment of \$250 is attached to provide for the small-entity fee for ten additional total claims.

If an extension of time for this paper is required, petition for extension is herewith made.

Respectfully submitted,

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